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9. 510(k) Summary

AUG - 3 2004

Company:	HOYA ConBio (formerly Continuum Electro-Optics, Inc.) 47733 Fremont Blvd Fremont, CA 94538 (800) 532-1064 phone (510) 445-4550 fax
Contact:	Jim Green Vice President of Engineering
Device Trade Name:	VersaWave Dental Er:YAG Laser System
Common Name:	Medical Laser System
Classification Name: Classification Code:	Instrument, surgical, powered, laser 79-GEX
Equivalent Device(s):	DELight Dental Er: YAG Laser System WaterLase, Millennium Dental Laser System Premier Centauri Dental Laser System
Intended Use:	The VersaWave Dental Er:YAG Laser System is intended for:

Hard Tissue
General Indications*

- Class I, II, III, IV and V cavity preparation
- Carries removal
- Hard tissue surface roughening or etching
- Enameloplasty, excavation of pits and fissures for placement of sealants

*For use on adult and pediatric patients

Root Canal Hard Tissue Indications

- Tooth preparation to obtain access to root canal
- Root canal preparation including enlargement
- Root canal debridement and cleaning

Root Canal Hard Tissue Indications

- Tooth preparation to obtain access to root canal
- Root canal preparation including enlargement
- Root canal debridement and cleaning

Bone Surgical Indications

- Cutting, shaving, contouring and resection of oral osseous tissues (bone)
- Osteotomy

Endodontic Surgery (Root Amputation) Indications

- Flap preparation – incision of soft tissue to prepare a flap and expose the bone

- Cutting bone to prepare a window access to the apex (apices) of the root(s).
- Apicoectomy – amputation of the root end.
- Root end preparation for retrofill amalgam or composite
- Removal of pathological tissues (i.e. cysts, neoplasm or abscess) and hyperplastic tissues (i.e. granulation tissue) from around the apex. *Note: Any tissue growth (i.e. cysts, neoplasm, or other lesions) must be submitted to a qualified laboratory for histopathological evaluation.*

Laser Periodontal Procedures

- Full thickness flap
- Partial thickness flap
- Split thickness flap
- Laser soft tissue curettage
- Laser removal of diseased, infected, inflamed, and necrosed soft tissue within the periodontal pocket
- Removal of highly inflamed edematous tissue affected by bacteria penetration of the pocket lining and junctional epithelium
- Removal of granulation tissue from bony defects
- Sulcular debridement (removal of diseased, infected, inflamed or necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility)
- Osteoplasty and osseous recontouring (removal of bone to correct osseous defects and create physiological osseous contours)
- Ostectomy (resection of bone to restore bony architecture, resection of bone for grafting, etc.)
- Osseous crown lengthening

Soft Tissue Indications Including Pulpal Tissues*

Incision, excision, vaporization, ablation, and coagulation of oral soft tissues, including:

- Excisional and incisional biopsies
- Exposure of unerupted teeth
- Fibroma removal
- Flap preparation-incision of soft tissue to prepare a flap and expose the bone.
- Flap preparation-incision of soft tissue to prepare a flap and expose the unerupted teeth (hard and soft tissue impactions)
- Frenectomy and frenotomy
- Gingival troughing for crown impressions
- Gingivectomy
- Gingivoplasty
- Gingival incision and excision
- Hemostasis and coagulation
- Implant recovery
- Incision and drainage of abscesses
- Incision and drainage of periapical abscesses
- Laser soft tissue curettage of the post-extraction tooth sockets and the periapical area during apical surgery

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- Leukoplakia
- Operculectomy
- Oral papillectomies
- Pulpotomy
- Pulp extirpation
- Pulpotomy as an adjunct to root canal therapy
- Reduction of gingival hypertrophy
- Removal of pathological tissues (i.e. cysts, neoplasm, abscess) and hyperplastic tissues (i.e. granulation tissue). *Note: any tissue growth (i.e., cyst, neoplasm or other lesions) must be submitted to a qualified laboratory for histopathological evaluation.*
- Root canal debridement and cleaning
- Soft tissue crown lengthening

- Treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa
- Vestibuloplaty

*For use on adult and pediatric patients

Comparison:	The VersaWave Dental Er:YAG Laser System, the DELight Er:YAG Laser System, the WaterLase, Millennium Dental Laser System, and the Premier Centauri Dental Laser System are equivalent in operating parameters, physical characteristics, and intended uses.
Nonclinical Performance Data:	None
Clinical Performance Data:	None
Additional Information:	None

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 3 2004

Mr. Jim Green
Vice President of Engineering
Hoya ConBio
47733 Fremont Boulevard
Fremont, California 94538

Re: K041710
Trade/Device Name: VersaWave Dental Er:YAG Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: June 18, 2004
Received: June 29, 2004

Dear Mr. Green:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

6. Indications for Use Statement

510(k) Number: K041710

Device Name: VersaWave Dental Er:YAG Laser System

Indications for Use:

Hard Tissue
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*For use on adult and pediatric patients

Prescription Use ____X____ OR Over-the-Counter Use_____
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041710